

Note to File:



Veterans Walk for Health Study

Site: _____

Site PI: _____

Subject ID: _____

Date: _____

GCP and Protocol Irregularities / Non-Compliance

Check all of the following that apply:

- ☐ Informed Consent Document not signed by patient before patient started the study
- ☐ Medical Clearance form not signed by physician before patient started the study
- ☐ Incorrect version of Informed Consent Document signed
- ☐ Inclusion/Exclusion criteria violated
- ☐ Patient in simultaneous interventional trials
- ☐ Required source data documentation could not be obtained
- ☐ Serious Adverse Event not reported appropriately to Ann Arbor
- ☐ Serious Adverse Event not reported appropriately to IRB
- ☐ Patient was seen outside the allowed visit interval
- ☐ Required study procedure not completed
- ☐ Other

Description: _____

Record of notification (check all that apply):

- ☐ Ann Arbor notified. Staff name and contact date: _____
- ☐ Event reported to site IRB. Date _____
- ☐ Event reported to Ann Arbor IRB. Date _____

Study Coordinator: _____ Date: _____
(Signature)

Site PI: _____ Date: _____
(Signature)

(File a copy of this form in the study binder and in the participant's study folder)